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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/224,556	12/30/98	DIXIT	V 203442102502

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HAYES, R	
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/224,556	Applicant(s) Dixit
	Examiner Robert C. Hayes	Group Art Unit 1647

☒ Responsive to communication(s) filed on *Jul 5, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *35-58* is/are pending in the application.

Of the above, claim(s) *39-42, 44-46, and 58* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *35-38, 43, and 47-57* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *35-58* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I (claims 35-38, 43 & 47) in Paper No. 9 is acknowledged. Claims 39-42 & 44-46 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected inventions. Election was made **without** traverse in Paper No.9.

2. Newly submitted claim 58 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claim 58 is the subject matter of non-elected Group V.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 58 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Specification

3. Claims 52-53 & 55-56 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, these claims have not been further treated on the merits. For examination purposes, these claims are being treated as being dependent on only claim 48.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 38 & 56 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, or does not require the hand-of-man. For example, the current recitation of "A host cell" encompasses a human organism. It is suggested that amending the claims to "an isolated host cell" should obviate this rejection.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 54 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context of that described within the specification at the time of filing the instant invention is apparent for the recitation, "wherein the carrier is a solid support". In contrast to Applicant's assertions on page 3 of the response, no

such basis is present on pages 10-11 nor 37 of the specification for *nucleic acid* compositions, "wherein the carrier is a solid support", versus the compositions on page 23 of the specification "containing any of the above mentioned *proteins, muteins, polypeptides or fragments thereof*"[emphasis added]; thereby, constituting new matter.

Additionally, no proper antecedent basis not conception in context of that disclosed within the instant specification exists for the broader concept of a nucleic acid "that is at least 90% homologous" *and* encodes a protein "*comprising* amino acids 297 to 567 as shown in SEQ ID NO:2". In contrast to Applicant's assertions on page 3 of the response, no such basis is present on pages 10-11 nor 37 of the specification. In contrast, page 11 of the specification contemplates a nucleic acid "that is at least 90% homologous" to the "nucleic acid molecules shown in Fig. 5" (i.e., SEQ ID NO:1); thereby, constituting new matter.

6. Claims 35-38, 43, 47-50 & 52-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification provides a written description of a single species of a nucleic acid encoding the human CD40 binding protein (CD40bp) of SEQ ID NO:2 (i.e., SEQ ID NO:1). No other species of CD40bp are described, or structurally contemplated, within the instant specification. Therefore, one skilled in the art also cannot reasonably visualize or predict what

critical nucleic acid residues would structurally characterize the genus of nucleic acids encoding the genus of CD40 binding proteins claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding CD40bp protein fragments (i.e., "*comprising* 297 to 567 as shown in SEQ ID NO:2"), or nucleic acids encoding CD40bp from any different species, which are further not described (i.e., as it relates especially to claim 48), or any different nucleic sequence that is "at least 90% homologous" to that depicted as SEQ ID NO:1, or any nucleotide sequence that encompasses unknown and undescribed promoter sequences, 5'- or 3'-flanking or enhancer regions, introns, allelic variants, or other sequences "comprising" any CD40 related nucleic acid sequence fragment; thereby, not meeting the written description requirement under 35 U.S.C. 112, first paragraph.

7. Claims 35-38, 43, 47-50 & 52-57 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the nucleic acid comprising SEQ ID NO:1, or a nucleic acid encoding the human CD40 binding protein (CD40bp) of SEQ ID NO 2, does not reasonably provide enablement for nucleic acid fragments encoding CD40 bp polypeptides that are structurally and functionally uncharacterized. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The recitation of a nucleic acid "that is at least 90% homologous" and encodes a protein "*comprising* amino acids 297 to 567 as shown in SEQ ID NO:2" sets forth little structural and

functional characteristics. Additionally, page 6 of the specification defines encoded CD40bp proteins as including "[biologically] functional equivalents", and "equivalents which *vary the primary sequence of the protein*"; thereby, encompassing any putative mutation, addition, deletion, truncation, substitution, etc. to the encoded human CD40bp protein of SEQ ID NO:2. In contrast, the instant specification provides no guidance as to what critical amino acids are required for any generic and active encoded CD40bp protein, or fragments thereof (i.e., as it relates especially to claims 35, 43, 48 & 57). Moreover, random mutations, substitutions, additions, deletions and truncations to a structurally undefined nucleic acid molecule would be predicted to adversely alter the biologically-active 3-dimensional conformation of the encoded protein; thereby, resulting in an inactive encoded CD40bp protein. For example, Rudinger teaches that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence"(see page 3). Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification, as to what alterations can be tolerated to maintain a functional polynucleotide encoding a CD40bp polypeptide would prevent the skilled artisan from determining whether any random mutation or fragment or functional equivalent encoded protein could be made that retains the desired function of the instant invention, without undue experimentation to determine otherwise. Thus, the

specification does not sufficiently structurally characterize and enable the breadth of the polynucleotide molecules currently encompassed by the claims, nor provides sufficient structural characterization to distinguish the polynucleotides of the instant invention from any different nucleotide sequences that possesses none of the desired functional properties of the invention; and as such, merely constitutes an invitation to experiment to discover how to make and use Applicants' invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 35-38, 43, 47-53 & 55-57 are rejected under 35 U.S.C. 102(a) as being anticipated by Hu et al. (IDS REF #20), Sato et al. (IDS REF #32), Mosialos et al. (IDS REF #26), or Cheng et al. (IDS REF #13).

Hu et al. teach the isolation of cDNA and mRNA encoding human CD40bp (e.g., Fig. 4), cloning into the expression vector, pcDNA3, followed by transfection into the isolated host cell, 293T, to produce the protein (e.g. pg. 30070 & Figs. 2-3; as it relates to claims 35-38, 43, 48-52 & 55-57). In that these nucleic acids are contained in solutions comprising water, which is an art recognized carrier, the limitations of claims 47 & 53 are also met.

Sato et al. teach isolation and sequencing of cDNA and mRNA encoding human CD40bp/CAP-1 (e.g., pg. 114-116 & Fig. 2), cloning into the expression vector, pSK-II, followed by transfection into the isolated host cell, RS11846 B-cell lymphoma cells, to produce the protein (e.g. pgs. 114-115 & Fig. 1; as it relates to claims 35-38, 43, 48-52 & 55-57). In that these nucleic acids are contained in solutions comprising water, which is an art recognized carrier, the limitations of claims 47 & 53 are also met.

Mosialos et al. teach isolation and sequencing of cDNA and mRNA encoding human CD40bp/LAP1 (e.g., pg. 390-392 & Figs. 1-3), cloning into the expression vector, pSA1, followed by transfection into the isolated host cell, BJAB B-lymphoma cells, to produce the protein (e.g. pgs. 395-396 & Figs. 2-3; as it relates to claims 35-38, 43, 48-52 & 55-57). In that these nucleic acids are contained in solutions comprising water, which is an art recognized carrier, the limitations of claims 47 & 53 are also met.

Cheng et al. teach isolation and sequencing of cDNA and mRNA encoding human CD40bp/CRAF1 (e.g., pg. 1495-1497 & Fig. 1), which is identical to the CD40 binding proteins CD40bp of Hu et al. and LAP1 of Mosialos et al. (pg. 1497, last paragraph, as it relates to a mammalian protein that binds the cytoplasmic region of CD40 receptor), cloning into the expression vector, pEBVHis A, followed by transfection into the isolated host cell, Ramos B cells, to produce the protein (e.g. pgs. 395-396 & Figs. 2-3; as it relates to claims 35-38, 43, 48-52 & 55-57). In that these nucleic acids are contained in solutions comprising water, which is an art recognized carrier, the limitations of claims 47 & 53 are also met.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
September 18, 2000

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